UNITED STATES PATENT AND TRADEMARK OFFICE

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570 West College Ave.
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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,031,007

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 6,031,007 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on February 17, 2004. The application was filed by Maillefer Instruments Trading S.a.r.l., an indirect wholly owned subsidiary of DENTSPLY International. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename ORAQIX having the active ingredients prilocaine and lidocaine. ORAQIX was approved for commercial use and sale by the Food and Drug Administration (FDA) on December 19, 2003.

A determination has been made that U.S. Patent No. 6,031,007 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ORAQIX.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that the active ingredients of ORAQIX were approved prior to the approval of ORAQIX. Lidocaine was previously approved for commercial use or sale in many products, including a topical ointment prior to January 1, 1982 (See the attached Orange Book search results for "Lidocaine"). Furthermore, the combination of lidocaine and prilocaine was also approved for commercial use or sale in many products, such as the product EMLA on December 30, 1992. Because the approval of ORAQIX **does not** represent the first permitted commercial marketing or use of either active ingredient of the product, the patent is not eligible for patent term extension. See Arnold Partnership v. Dudas, 70 USPQ2d 1311 (CA FC 2004) (Patent term restoration statute, 35 U.S.C. §156, which does not permit extension of term for drug product patent unless applicant's permission to market product is "first permitted commercial marketing or use," is properly interpreted to apply to drug patent with two active ingredients only if one of those active ingredients has not been previously marketed, since language of statute requires examination of patent's eligibility for extension on component-by-component basis, and is not susceptible of alternate reading that would allow extension for patent with two previously marketed active ingredients if combination thereof is new to marketplace).

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter*

alia, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,031,007 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredients in the approved product ORAQIX are prilocaine and lidocaine. As indicated in the Food and Drug Administration's "Orange Book," the active ingredients prilocaine and lidocaine had been approved for commercial marketing and use prior to the approval of the applicant's product. Furthermore, the prior approval of the active ingredients prilocaine and lidocaine in EMLA by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product ORAQIX occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product, ORAQIX, does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of ORAQIX (prilocaine and lidocaine) was not the first permitted marketing or use of either the active ingredient thereof, the patent is not eligible for patent term extension based upon the regulatory review of ORAQIX. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990); and Arnold Partnership, 70 USPQ2d 1311.

In view of the above, the term of U.S. Patent No. 6,031,007 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ORAQIX and the application for patent term extension, filed February 17, 2004, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7744

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744. E-mail inquiries should be directed to Karin.Ferriter@uspto.gov.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ORAQIX

Enclosure: Search Results from the Orange Book- Lidocaine
Lidocaine and Prilocaine

Search results from the "OB_Rx" table for query on "080198."

Active Ingredient:	LIDOCAINE
Dosage Form;Route:	OINTMENT; TOPICAL
Proprietary Name:	LIDOCAINE
Applicant:	FOUGERA
Strength:	5%
Application Number:	080198
Product Number:	001
Approval Date:	Approved Prior to Jan 1, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AT**
Patent and Exclusivity Info for this product:	View

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Orange Book Data Updated Through December, 2004
Orange Book Patent Data Only - **Daily**
Patent Data Last Updated: January 28, 2005

Search results from the "OB_Rx" table for query on "019941."

Active Ingredient:	LIDOCAINE; PRILOCAINE
Dosage Form;Route:	CREAM; TOPICAL
Proprietary Name:	EMLA
Applicant:	ASTRAZENECA
Strength:	2.5%;2.5%
Application Number:	019941
Product Number:	001
Approval Date:	Dec 30, 1992
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
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Orange Book Patent Data Only - **Daily**
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